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| 09/700,492      | 01/05/2001  | Stephen G. Oliver    | 39-225              | 6022             |

7590

07/01/2002

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| EXAMINER |
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LAMBERTSON, DAVID A

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1636

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/700,492

Applicant(s)

OLIVER ET AL.

Examiner

David Lamberson

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --  
Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-9,35 and 37 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,10-12 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 35, 37 and 38, drawn to genetically modified yeast strains containing the SRB1/PSA1 and PKC1 genes expressed from heterologous inducible promoters and their first appearing utility comprising a method for efficient cell lysis.

Group II, claim(s) 13 and 14, drawn to a method for using genetically modified yeast strains, containing the SRB1/PSA1 and PKC1 genes expressed from heterologous inducible promoters, for improved protein isolation.

Group III, claim(s) 15-23, drawn to a method for regulating flocculation using genetically modified yeast strains containing the SRB1/PSA1 and PKC1 genes expressed from heterologous inducible promoters.

Group IV, claim(s) 24-31, drawn to a method of fermentation using genetically modified yeast strains containing the SRB1/PSA1 gene expressed from a heterologous inducible promoter.

Group V, claim(s) 32-34, drawn to a method of fermentation using genetically modified yeast strains containing the SRB1/PSA1 and PKC1 genes expressed from heterologous inducible promoters.

The special technical feature of Group I which defines an advance over the art is the use of strains containing inducible SRB1/PSA1 and PKC1 genes to modulate the integrity of the cell wall of yeast to control the susceptibility of the cells to lysis. The special technical feature of Group II involves the use of strains containing inducible SRB1/PSA1 and PKC1 genes to modulate the integrity of the cell wall of yeast for the purpose of isolating proteins from cells. This feature defines an advance over Group I in that it involves additional steps in the isolation of a protein (as opposed to obtaining a cell lysate which would contain numerous additional

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proteins), wherein the method of Group II is not suggested or obvious over the method of Group I.

The special technical feature of Group I which defines an advance over the art is the use of strains containing inducible SRB1/PSA1 and PKC1 genes to modulate the integrity of the cell wall of yeast to control the susceptibility of the cells to lysis. The special technical feature of Group III involves the use of strains containing inducible SRB1/PSA1 and PKC1 genes to regulate flocculation of cells. This feature defines an advance over Group I in that it involves an additional process (which need not be related to cell lysis), wherein the method of Group III is not suggested or obvious over the method of Group I.

The special technical feature of Group I which defines an advance over the art is the use of strains containing inducible SRB1/PSA1 and PKC1 genes to modulate the integrity of the cell wall of yeast to control the susceptibility of the cells to lysis. The special technical feature of Group IV involves the use of strains containing an inducible SRB1/PSA1 gene to regulate fermentation of cells. This feature defines an advance over Group I in that it involves an additional process (which need not be related to cell lysis), wherein the method of Group IV is not suggested or obvious over the method of Group I.

The special technical feature of Group I which defines an advance over the art is the use of strains containing inducible SRB1/PSA1 and PKC1 genes to modulate the integrity of the cell wall of yeast to control the susceptibility of the cells to lysis. The special technical feature of Group V involves the use of strains containing inducible SRB1/PSA1 and PKC1 genes to regulate fermentation of cells. This feature defines an advance over Group I in that it involves an additional process (which need not be related to cell lysis), wherein the method of Group V is not suggested or obvious over the method of Group I.

During a telephone conversation with Mary J. Wilson on June 12, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12, 35, 37 and 38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim cells that express the SRB1/PSA1 and PKC1 genes or functional derivatives thereof from an inducible promoter, and the use of these strains in a method of improved cell lysis resulting from repressing the expression of said genes or functional derivatives thereof, in turn leading to a compromised cell wall. Applicants provide a written description on only the use of the SRB1/PSA1 and PKC1 genes to generate these cells and perform this method. Applicants' claims read on a genus of genes capable of generating these cells and performing this method.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by

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disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the term “functional derivatives thereof”, when referring to PKC1 and SRB1/PSA1, implies either that a structure-function relationship or a family of acceptable genes is included within the limitations of the claims. Applicants have not provided a written description of examples of “functional derivatives” that may act as substitutes for said genes. Alternatively, applicant has not provided a written description of a structure-function relationship as it pertains to said genes and “functional derivatives thereof”. Applicants claim the components of the cells and method by function only, without any disclosed or known correlation between the structure of said elements and their function. For example, would a mammalian PKC1 orthologue represent a functional derivative, although it is unclear that the mammalian gene reasonably affects cell wall integrity? In addition, would a gene with Pkc1-like activity be a suitable “functional derivative” within the limitations of the claim? What functions of PKC1 are required for its use in the invention (e.g., kinase activity)? Are all functions of said genes required? As applicants have only disclosed a written description for the indicated genes and not for a representative number of species through specific identifying characteristics or a structure-function relationship, they have not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 35, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the definition of "functional derivatives thereof" is in terms of a relationship to the SRB1/PSA1 and PKC1 genes, making the claim indefinite. For example, what mutations and/or deletions of said genes are acceptable to constitute a "functional derivative"? Additionally, are homologues of said genes acceptable as "functional derivatives", or are the claims limited to the specific alleles present in the yeast species suggested by the applicant.

### *Specification*

The disclosure is objected to because of the following informalities: the word "inducible" is misspelled as "inducable" throughout the specification.

Appropriate correction is required.

Claims 1-12, 35, 37 and 38 are objected to because of the following informalities: the word "inducible" is misspelled as "inducable". Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

June 28, 2002

DAVID GUZO  
PRIMARY EXAMINER  
